

REMARKS/ARGUMENTS

Claims 20-28, 30 and 44 are active. Claims 29, 31-43 and 45 have been withdrawn from consideration. New Claims 46-47 are presented.

The specification has been revised to remove the term http:// as suggested by the Examiner and delete the term “claim”. Also, the word “claim” has been removed from certain segments of the specification.

Claims 20, 31 and 42 have been amended for clarity. New Claim 46 finds support in the paragraph bridging pages 17-18 of the specification. Claim 47 finds support on page 22, lines 3 ff. of the specification. No new matter has been added.

Restriction/Election

The Applicants previously elected with traverse Group I, Claims 1, 2, 4, 5, 7 and 18. These claims are directed to polynucleotides encoding a polypeptide that binds to WF00144, their complements, vectors and transformants. SEQ ID NOS: 1 and 2 were indicated as being subject to examination in the last Official Action.

WF00144 is a pharmaceutically active substance described on page 2, second full paragraph of the specification. Claims 3, 6, 8-17 and 19 were withdrawn from consideration. The present claims correspond to the elected subject matter except as follows. Claims 29 and 40 are directed to a method of making a polypeptide which binds to WF00144. Claims 42-45 are directed to subject matter covered by nonelected Claims 10, 11 and 14. These claims depend from, or otherwise include the limitations of the elected claims and the Applicants respectfully request that they be rejoined now or upon an indication of allowability for a corresponding elected product claim.

Objection--Specification

Pages 26 and 27 of the specification were objected to as containing a hyperlink. This objection is moot in view of the amendments above. The Applicants thank Examiner Mitra for indicating that dropping “http:” would resolve this objection.

The Title has been amended and the continuity date appears in the attached Supplemental Application Data Sheet (“ADS”). According to MPEP 601.04 the ADS is part of the application for which it has been submitted (37 C.F.R. §1.76) and may be filed to correct Application information such as the Title and Domestic Priority Information. When domestic priority information appears on the ADS this “constitutes the specific reference required by 35 U.S.C. 119(e) or 120”. Thus, the Applicants respectfully submit that these objections are now moot.

Rejection—35 U.S.C. 112, first paragraph

Claims 20, 21, 25, 26, 30 and 44 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate enablement. While enablement for the specific isolated polynucleotide sequence of SEQ ID NO: 1 is acknowledged, the Official Action questions the enablement of polynucleotides which have at least 96% sequence identity with SEQ ID NO: 1 or fragments or variants of this sequence.

The rejection indicates that it would be overcome by amending the claims to recite one of the hybridization conditions on page 14 of the specification. Claims independent Claims 21, 31 and 42 already recite these hybridization conditions. Moreover, these claims are directed polynucleotides which encode functional polypeptides which bind to WF00144. Screening a peptide for its ability to bind to WF00144 would be routine for one of skill in the art who generally has a graduate degree or post-graduate training and specific binding of the human 35kDa protein to WF00144 is exemplified starting at the bottom of page 41 of the

specification. Therefore, one with skill in the art could easily identify peptides which bind to WF00144 based on the high level of skill in the art and on the disclosure and examples in the specification. According, the Applicants respectfully request that this rejection be withdrawn.

Claim 30 was rejected as not enabled on the grounds that it encompasses polynucleotides “consisting of at least 15 consecutive bases” of the polynucleotide of Claim 20. Claim 30 is a dependent claim which covers fragments of the polynucleotide of Claim 20 which encode polypeptides that bind to WF00144. For the reasons discussed above, no undue experimentation would be required by one of skill in the art to identify a fragment encoding a polypeptide which binds to WF00144 since the level of skill is high and the screening procedures for peptides that bind to WF00144 simple and exemplified in the specification. “The test [for undue experimentation] is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine”, *Johns Hopkins University v. Cellpro, Inc.*, 47 USPQ2d 1705 (Fed. Cir. 1998). Here, the experimentation is routine and merely involves determining whether an encoded polypeptide binds to WF00144 using a method exemplified in the specification. Moreover, the scope of the claimed subject matter is structurally limited and does not read on an unlimited genus of DNA sequences. The Applicants respectfully request that these grounds of rejection be withdrawn for the reasons discussed above.

Rejection—35 U.S.C. 112, first paragraph

Claims 20, 21, 25, 26, and 30 were rejected under 35 U.S.C. 112, first paragraph, as lacking adequate written description.

Explicit description of claim limitations. As an initial matter, the specification provides explicit written description of “a polynucleotide having at least . . . 96% homology to

the base sequence of SEQ ID NO: 1" (page 7, lines 14-16) "encoding a protein that specifically binds to a substance WF00144" (page 7, lines 1-3). Therefore, there is no issue of literal description of the limitations in these claims. Moreover, there is no requirement that a specification exemplify the claimed subject matter in order to describe it.

The underlying concern appears to be that the specification does not describe the invention since it does not present a detailed structure/function analysis of which alterations to the primary structure of a polypeptide would yield proteins that bind to WF00144. However, as discussed above with regard to enablement, it would be a routine matter to identify functionally active proteins that bind to WF00144 without undue experimentation. Clearly, the Applicants possessed the claimed subject matter at the time of invention based on its explicit description in the specification. Accordingly, they respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. 102

Claims 20-22, 24, 27 and 28 were rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Tang et al., U.S. 60/336,453, and Strausberg et al., PNAS 99:16899. These rejections are traversed, since the prior art does not disclose with sufficient specificity isolated polynucleotides encoding polypeptides which bind to WF00144.

Tang et al., U.S. 2004/0219521, does not disclose or suggest the limited genus of polynucleotides of the present invention, nor does it suggest selecting those DNAs encoding polypeptides which bind to the drug WF00144.

Tang discloses a huge genus of DNA sequences as well as sequences cross-hybridizing to this huge genus of sequences [0010]. Therefore, Tang does not disclose the present invention with sufficient specificity to amount to anticipation, specifically suggest the subgenus of polynucleotides encoding polypeptides which bind to the drug WF00144, nor

provide a reasonable expectation of success about how to use the polynucleotides of the invention.

Similar considerations apply to Strausberg et al. which describes “more than 15,000 full-length human and mouse cDNA sequences”, see Title.

The cited prior art does not disclose all the limitations of the invention, namely that the polynucleotides encode polypeptides binding to WF00144. While the Official Action asserts that the prior art polynucleotides would inherently encode polypeptides that bind to WF00144, it provides no logical reason or technical argument explaining why the prior art polypeptides would have this activity. At best the prior art merely describes a huge genus of polynucleotides some of which might encode polypeptides that bind to WF00144. Prior art may anticipate a claim if it does not explicitly disclose a feature of the invention (i.e., binding to WF00144), however, that feature must be *necessarily* present in the prior art.

[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is *necessarily* present, or inherent, in the single anticipating reference (emphasis added). *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 [20 USPQ2d 1746] (Fed. Cir. 1991).

Here, the Office has not shown that the cited prior art discloses a polynucleotide encoding polypeptide which bind to WF00144 or provided any rational basis for asserting this. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. 102

Claim 21 and 30 were rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Valenzuela et al., WO 2000/49134. The Applicants traverse this rejection since Claims 21 and 30 are directed to polynucleotides and do not read on a single amino acid residue, such as glycine.

Valenzuela discloses a short sequence match between nucleotides 752-770 of SEQ ID NO: 1 and a sequence in the search database. However, the database sequence is not an isolated sequence as required by Claims 21 and 30, but is an embedded part of a longer sequence.

These claims each require that the polynucleotide encode a polypeptide that binds to WF00144 and the Office has not shown this.

[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is *necessarily* present, or inherent, in the single anticipating reference (emphasis added). *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 [20 USPQ2d 1746] (Fed. Cir. 1991).

Here, the Office has not shown that the polypeptide encoded by Valenzuela polynucleotide necessarily binds to WF00144. Moreover, the Office has not expressed any logical reason why such a polypeptide would bind to WF00144. Accordingly, since Valenzuela does not disclose an isolated polynucleotide meeting the structural limitations of the rejected claims and there is no good reason to expect that the Valenzuela polypeptide would bind to WF00144 as required by these claims, the Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification of such is earnestly requested.

Respectfully submitted,

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